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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0268]

Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation.'' This guidance provides recommendations on the container closure systems information that applicants should provide to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in support of new drug applications, abbreviated new drug applications, biologics license applications, and supplements to these applications.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the

draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

W. Mike Adams, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7310, or

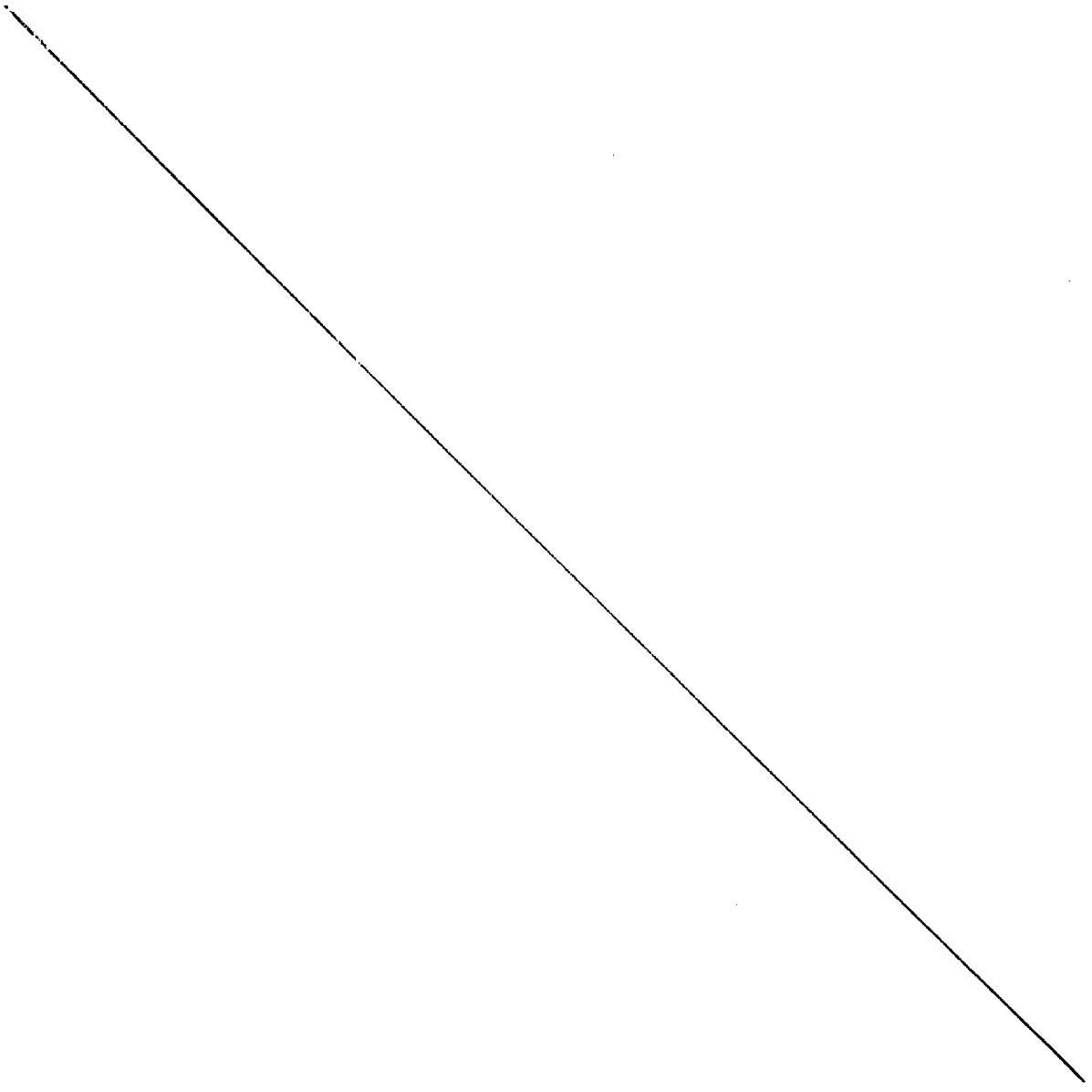
John D. Finkbohner, Center for Biologics Evaluation and Research (HFM–676), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301827–3031.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation.'' This guidance provides recommendations on the container closure system information that applicants should provide to CDER or CBER for initial applications and supplements. In addition, the document provides guidance on qualification and quality control of packaging components used for particular dosage forms and routes of administration, including the following: Drug products for injection and ophthalmic drug products, liquid-based oral and topical drug products and topical delivery systems, solid oral dosage forms and powders for reconstitution, and other dosage forms. This guidance supersedes the agency's ''Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics,'' issued February 1987.

This Level 1 guidance is being issued consistent with FDA's good guidance practice (62 FR 8961, February 27, 1997). In the **Federal Register** of July 15, 1997 (62 FR 37925), FDA announced the availability of a draft version of this guidance. The July 1997 document gave interested persons an opportunity to submit comments through September 15, 1997. On September 5, 1997, in response to requests from the public, the agency extended the comment period until November 14, 1997 (62 FR 46980). All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of public input during the comment period, the final guidance is clearer and more concise than the

draft version. The guidance represents the agency's current thinking on submitting information in drug applications on container closure systems used in packaging human drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except



that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/29/99

June 29, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy Coordination

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